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Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

Comment On: NRC-2017-0215-0001
Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance for Comment

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Submitter Information

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General Comment

Dear Nuclear Regulatory Commission,

I am a practicing interventional radiologist/oncologist at Massachusetts General Hospital and an Assistant Professor of Radiology at Harvard Medical School, and have been practicing for over 8 years. I have utiilzed Y-90 radioembolization on hundreds of patients over that time, and I am an authorized used for both Sir-Spheres and Theraspheres at my hospital. I have worked closely with Sirtex for may years in treating my patients. I endorse the Sirtex response to the NRC proposed amendment, which is supplied below.

Thank you for your consideration,

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM -03
Add= L. Dimmerick (LCD1)

Suvranu Ganguli, MD

Attachments

Sirtex Response to NRC Proposed Changes Oct 2016

SIRTeX

Sirtex Response to Proposed Changes to the
Yttrium-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance
Statement to the U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
October 7, 2016

Proposed Policy Change

The Nuclear Regulatory Commission (NRC) is proposing removal of "Pathway 2" from the Authorized User (AU) Training and Experience section, Item B, in the February 12, 2016, *Yttrium-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance*, hereafter referred to as the NRC guidance

Intended Consequence

The NRC is proposing that only an AU for yttrium-90 (Y-90) microsphere technology be allowed to oversee the training of a new physician for that particular Y-90 microsphere technology. Manufacturer representatives (i.e. Proctors and/or Sales Representatives) would not be allowed to supervise *in-vitro* or *in-vivo* cases for the purpose of a new physician becoming an AU for Y-90 microsphere technology.

Unintended Consequence

If Pathway 2 is removed in its entirety Y-90 manufacturers will not be able to open new accounts, thereby limiting patient access to this life extending technology.

Explanation

In general practice, Pathway 2 inherently provides "provisional" licensing authorization for physicians at sites that do not currently use Y-90 microspheres. Non-physician manufacturer representatives provide three (3) *in-vitro* simulated cases for a physician at a new site to be named as an AU on the license. The *in-vitro* training provides a working knowledge of Y-90 microspheres in accordance with NRC guidance Section A.3.iii. Following the "provisional" license amendment, the site is then allowed to order Y-90 microspheres from the manufacturer, which will subsequently be utilized via the first three (3) *in-vivo* patient cases. These *in-vivo* patient cases are supervised by a manufacturer representative for each type of Y-90 microsphere for which the physician is authorized.

Without the ability to "provisionally" amend a license naming an AU, it would be impossible to order and receive the Y-90 microspheres for the *in-vivo* supervised training at the facility in compliance with 10 CFR 35.11, "License Required." In other words, sites cannot order Y-90 microspheres, if they are not licensed to possess them, which require an AU on the license. The site cannot name an AU on the license until the site has possessed Y-90 microspheres for the AU to undergo the *in-vivo* supervised training. It is the proverbial "Chicken or the egg."

A majority of physicians coming out of a Fellowship program do not have the required hands-on experience to become an AU for SIR-Spheres Y-90 resin microspheres (i.e. not every program offers hands-on experience for fellows). This applies to Interventional Radiologists (IRs), Nuclear Medicine physicians, and Radiation Oncologists. SIR-Spheres Y-90 resin microspheres must be an integral part of all Fellowship programs and included in board certification processes before Pathway 2 can be removed in its entirety.

For Sirtex, removal of Pathway 2 would mean that all potential AU physicians must gain hands-on experience with SIR-Spheres Y-90 resin microspheres either during Fellowship or at an existing site previously authorized for the medical use of SIR-Spheres Y-90 resin microspheres. This was not possible in 2011 when the NRC guidance was originally revised to include a manufacturer pathway and is still not possible now for several reasons:

1. A physician without prior hands-on experience would be required to obtain the experience by going to another hospital that is currently using SIR-Spheres Y-90 resin microspheres. Unfortunately, a physician rarely has credentials or privileges to practice medicine at sites other than his or her own. A physician visiting another site would not be allowed to touch the patient or product; therefore negating the "hands-on experience."

2. Some sites use a "two-physician model" (e.g., Radiation Oncologist AU and IR as a non-AU team member). An IR who performs procedures would not likely receive a preceptor statement from a radiation oncologist AU in order for the IR to apply for AU status at a new facility and vice versa. This is evident when IRs try to obtain preceptor letters from fellowship when a non-IR served as the AU on the radioactive material license (RAML) at the fellowship facility. When a physician comes from a two-physician model site where they cannot receive sign-off for previous casework, another option must exist for that physician to become an AU at a new facility.

Sirtex Proposal

Sirtex recommends retaining Pathway 2. Pathway 2, as it currently stands, not only allows manufacturers to provide thorough and comprehensive training and clinical-use experience for new Y-90 microsphere users in the safe and effective use of the technology, but also allows

manufacturer representatives to satisfy the real-world need to provisionally train new AUs at sites without an existing Y-90/Selective Internal Radiation Therapy Program in a timely manner.

Additional Background on Sirtex Training Program

Sirtex received U.S. Food and Drug Administration (FDA) premarket approval with a requirement to only supply SIR-Spheres Y-90 resin microspheres to trained users. This is reflected in the Sirtex SIR-Spheres Y-90 resin microspheres labelling in that, "Only doctors qualified and licensed under Title 10 Code of Federal Regulations Part 35 (Nuclear Regulatory Commission) and trained under the Sirtex [Training, Education and Certification] TEC training program may order and implant SIR-Spheres microspheres." As a part of the TEC program, Sirtex provides a robust training program for all new physicians who wish to use SIR-Spheres Y-90 resin microspheres such as an Interventional Radiologist (IR). Noting that the IR plays a critical part in ensuring safe delivery of the product to the patient, the Sirtex TEC program utilizes Sirtex trained and board certified Interventional Radiologists to instruct all new physician users involved in the clinical use of SIR-Spheres Y-90 resin microspheres.

The Sirtex trained and certified Interventional Radiologist may or may not be an AU named on a RAML, depending on whether his/her site operates under a one-physician or two-physician model. Sirtex only utilizes Interventional Radiologists as proctors because a Radiation Oncologist or Nuclear Medicine physician would not be qualified to oversee all critical components of training, including mapping the patient's vascular anatomy or ensuring proper catheter placement. Sirtex proctors are able to provide training on radiation dosimetry and safe handling of SIR-Spheres Y-90 resin microspheres. Sirtex physician proctors are selected because they are active expert users of SIR-Spheres Y-90 resin microspheres with some 159 years combined experience performing up to 400 procedures per year. All new physician users are certified by a Sirtex Medical Director, based on feedback of successful training from Sirtex proctors. Sirtex proctors help an institution build a sustainable, high-quality program that is consistent with Sirtex standards and Federal and state regulatory requirements.

The Sirtex TEC program will continue irrespective of the NRC's AU training and experience requirements, as Sirtex has a training commitment to the FDA.

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